



2/26/93  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB 26 1993

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCESMEMORANDUM

SUBJECT: Myclobutanil

FROM: Anthony F. Maciorowski *Anthony F. Maciorowski*  
Ecological Effects Branch  
Environmental Fate and Effects Division (H7507C)

TO: Julie Fairfax, PM Team 21  
Fungicide\Herbicide Branch  
Registration Division (H7505C)

TOPIC

EEB received a letter from Rohm and Haas 2/12/93 outlining their concerns regarding EEB's risk assessment. Rohm and Haas would like to register myclobutanil for use on turf for the 1993 use season. A copy of this letter is attached.

BACKGROUND

The initial turf petition, involving maximum use rates of 1.4 lbs ai/acre, was reviewed on August 15, 1990. EEB was unable to assess the chronic hazard to birds as the two avian reproduction studies that had been performed in 1987 tested levels much lower than the estimated environmental concentration (EEC). [Test levels of 6 and 60 ppm were employed and no effects were observed, but based on Kenaga, levels ranging from 786 (average) to 1268 (maximum) ppm were expected on short grass].

A rebuttal to the original turf review was submitted to EEB in 1992. In the two year lapse between the submission of the avian reproduction studies and the rebuttal, numerous other myclobutanil registration petitions were received. Repeatedly, the chronic hazard to birds could not be evaluated due to insufficient data on avian reproduction studies. The turf rebuttal employed different use rates than the original review. EEB still needs the complete label.



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Using .65 lbs ai/acre, Rohm and Haas' reported new maximum use rate, the revised EECs on turf are 527 (ppm) average and 1015 ppm (maximum). The EECs still greatly exceed the maximum level Rohm and Haas tested in the avian reproduction studies and no suitable residue data has been submitted by the company. At the present time, EEB has insufficient data to determine the avian chronic level of concern (LOC).

#### CONCLUSIONS

The new paradigm depends on adequate acute and chronic laboratory toxicity data for EEB to determine if the LOC is exceeded. Laboratory toxicity data on avian reproduction are still lacking for myclobutanil's turf use. EEB still believes that this is an important endpoint of concern. After the avian reproduction data is submitted and reviewed, EEB will determine if the LOC for avian reproductive effects is exceeded. If the levels are exceeded, EEB will welcome discussions on risk mitigation with Rohm and Haas.

EEB would like to meet with Julie Fairfax and Frank Sanders to discuss the above issues in greater detail.

300 WALL WEST PHILADELPHIA, PA. 19105, U.S.A. TELEPHONE (215) 592-3000  
 FAX: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377



February 12, 1993

Dr. Tony Maciorski  
 Chief, Ecological Effects Branch  
 Office Of Pesticide Programs  
 US Environmental Protection Agency  
 1921 Jefferson Davis Highway  
 Arlington, VA 22202

Dear Dr. Maciorowski:

I generally leave product-related issues to the registration product managers within our regulatory affairs department at Rohm and Haas. However, we have one particular case where I would like to have a direct discussion with you to try and resolve an impasse which we currently face with your branch. The case is myclobutanil, an active ingredient first registered with the Agency in 1989 for use on apples and grapes. Rohm and Haas would like to extend the use to include turf for homeowner use and for use on turf farms, golf courses, cemeteries, etc. An application for this use has been pending since 1989 during which time numerous letters have been exchanged, studies have been reviewed and meetings have been attended.

Rohm and Haas would like to initiate sales for the 1993 use season for myclobutanil for turf under the tradename Eagle. For this to happen, we need to get agreement from EEB within the next few weeks that there is no unreasonable risk to the environment from the use of Eagle. As I understand it, there is only a single issue that needs to be resolved that would justify a permanent, or at least, a conditional registration. That issue is the risk to avian species who might ingest Eagle-treated turf on a golf course. In a sense, Rohm and Haas created this problem for itself since the avian reproduction studies, which we conducted in the mid-eighties to support the registration on grapes and apples, tested at a high dose of 60 ppm. Although no adverse effects were seen at this high dose, the EEC which your branch has calculated is higher than the 60 ppm high dose. A number of meetings have been held to debate the method of calculation of the EEC but no agreement has yet been achieved.

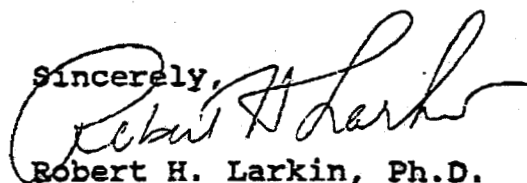
Rohm and Haas has now committed to repeat the avian reproduction studies at higher doses, and the protocols have been submitted for review. We are confident that the NOEL will be demonstrated to be significantly higher than 60 ppm and thus will alleviate the concerns of your scientists. However, these studies will not be available until late 1993 and will, at best, allow us to begin sales in the 1994 use season. I would like to discuss with you the possibility of obtaining a conditional registration for 1993 based on mitigation measures that Rohm and Haas would add to its Eagle label in the spirit of the new risk assessment paradigm published

I asked to copy the PM →

by Linda Fisher. A meeting to discuss these mitigation measures was scheduled by the Registration Division for this past Wednesday, February 10. Although four representatives from Rohm and Haas traveled to Washington to attend the meeting, EEB scientists were not able to attend and no progress was made. I would like to meet with you and appropriate scientists from your branch, if you choose, to try and resolve this issue. I am confident that we could achieve resolution if we get the right people together.

To this end I would like to meet with you as soon as possible. Except for Friday morning, I am available to meet with you at any time of any day next week. Please call me (215-592-2078) with a proposed meeting date or if you need more information. Thanks in advance for your help with this issue.

Sincerely,



Robert H. Larkin, Ph.D.

Director

Agricultural Chemicals Registration  
and Regulatory Affairs Department

*meet  
w/ R. Larkin*

MYCLODUTANIL

#7505C